Applicants thank the Examiner for consideration of the subject patent application. In the office action mailed September 25, 2007, Claims 1-24 were pending. Claims 11-24 have been withdrawn subject to a restriction requirement. Claims 25-36 have been added.

Reconsideration of the application is respectfully requested in view of the following responsive remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

In the Office Action of September 25, 2007 the following actions were taken:

(1) The Oath and Declaration has been objected to as listing an incorrect filing date; and

(2) Claims 1-10 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 4,151,273 (hereinafter "Riegelman") in view of U.S. Patent No. 4,098,802 (hereinafter "van der Vies").

It is respectfully submitted that the presently pending claims be allowed based on the remarks below.

Claim amendments

Applicants have added Claims 25-36. Claims 25-36 have been added in accordance with embodiments of the present invention. Support for the claims can be found in original claims 1-10; page 9, lines 32-33; page 10, lines 1-2; and Examples 1-9.

Oath and Declaration

Applicants have submitted a corrected Oath and Declaration with the correct dates. As such, Applicants respectfully request the Examiner to withdraw the present objection.

Rejections Under 35 U.S.C. § 103

The Examiner has rejected Claims 1-10 under 35 U.S.C. 103(a) as being allegedly unpatentable over Riegelman in view of van derVies.

The Applicant does not deem it necessary to recite the entire case law standard required in

order to establish a *prima facie* case of obviousness. However, the Applicant would like to briefly remind the Examiner of the required three criteria for a *prima facie* case of obviousness, namely 1) that the asserted references as modified or combined must teach or suggest each and every element of the claimed invention, 2) that the asserted references as modified or combined must provide a sufficient likelihood of successfully making the modification or combination, and 3) that the Examiner must identify a reason for the modification or combination asserted. As the Examiner has used Riegelman and van der Vies in rejecting the present claim set, a brief discussion of these references is provided below.

Riegelman

Riegelman provides methods for increasing absorption in aqueous gastric fluids of insoluble or relatively insoluble drugs. See col. 1, lines 41-45. Riegelman provides a laundry list of 23 drugs and drug types. See col. 2, lines 13-24. However, Riegelman is directed at griseofulvin as it only exemplifies griseofulvin. See Examples 1-11 and claims. As noted by the Examiner, Riegelman does not teach the percent weight of polyethylene glycol carrier or a specific dose of testosterone.

van der Vies

van der Vies teaches oral pharmaceutical preparations of one or more esters of testosterone derived exclusively from aliphatic carboxylic acids having 9-16 carbons. See Abstract. As noted by the Examiner, van der Vies exemplifies 10 mg, 25 mg, and 30 mg of a testosterone ester; however, such disclosure is limited to testosterone esters having 9-16 carbon acids. Notably, van der Vies does not disclose that the amount provides a testosterone serum level of 15ng/dl to 1200 ng/dl.

Claims 1-10

The Examiner has alleged that Riegelman discloses all the claim elements of independent Claim 1 except for the wt% of the polyethylene glycol carrier and the amount of testosterone. However, Applicants submit that Riegelman also fails to disclose that the testosterone provides a testosterone serum level of about 15ng/dl to about 1200 ng/dl. As such, Riegelman fails to disclose at least three elements as cited in independent Claim 1.

The Examiner combines Riegelman with van der Vies as allegedly teaching the amount of testosterone as presently claimed. However, the present claims recite that the testosterone is in a polyethylene glycol carrier (PEG) comprising 30% w/w to about 80% w/w having a molecular weight (MW) of about 100 to about 20,000 with a therapeutically effective amount of testosterone in the carrier ranging from about 2.5 mg to about 45 mg such that the formulation provides a testosterone serum level ranging from about 15ng/dl to about 1200 ng/dl. In other words, each the first three elements: PEG, MW, and testosterone must be combined to provide the serum level. As such, the serum level is not merely inherent in the composition but acts as a separate element that must be fulfilled in order to read on the present claims. In other words, Applicants are not claiming that every combination of PEG, MW, and testosterone will produce the recited serum levels. As such, in order to establish a prima facie case, the Examiner must show that the prior art, alone or in combination, teaches a formulation within the recited ranges that provides the presently claimed serum levels. To be clear, Applicants submit that a formulation within the claimed compositional ranges that does not provide the claimed serum levels would not be covered by the claim set.

As such, Applicants submit that the van der Vies's disclosure of an ester of testosterone in an amount of 10, 25, or 30 mg does not read upon the present claim set. Applicants submit that the Examiner must also show that the amount could be combined with a PEG having a MW that provides the claimed serum levels. The Examiner has alleged that the serum levels would fall within the claimed range since van der Viels teaches the same amount of testosterone. However, the amount of testosterone is but one claim element that can affect the serum level. In other words, Applicants submit that percent weight of the carrier and the MW of the carrier also affect

the serum level. For example, the amount of the carrier and the MW of the carrier can provide substantial changes in the rates of diffusion of the testosterone from the formulation. As such, the blood serum levels would be affected. Applicants submit that the present combination fails to disclose a blood serum level achieved by the use of a polyethylene glycol carrier (PEG) comprising 30% w/w to about 80% w/w having a molecular weight (MW) of about 100 to about 20,000 with a therapeutically effective amount of testosterone in the carrier ranging from about 2.5 mg to about 45 mg. As such, Applicants submit that the present combination fails to teach each and every element of the pending claim set and respectfully requests that the Examiner withdraw the present rejection.

Additionally, Applicants wish to address independent Claim 10. Applicants note that van der Vies only teaches amounts of testosterone esters (esterified with aliphatic groups having 9-16 carbons) and does not teach testosterone. As such, Applicants note that the present combination fails to teach an amount of testosterone in addition to the weight percent of the polyethylene glycol carrier. Therefore, Applicants contend that the present combination fails to teach each and every element with respect to Claim 10 and respectfully request that the Examiner withdraw the present rejection.

CONCLUSION

If any impediment remains to examination after consideration of the above-recited remarks, which could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, at (801) 566-6633 so that such issues may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. 20-0100.

DATED this 26th day of December, 2007.

Respectfully submitted,

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